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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,194	08/15/2002	Michel Renard	218874USOPCT	8696

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,194	RENARD ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-0-0

DETAILED ACTION

1. Claims 1-11 including SEQ ID NO:4, 5, and 6 are pending and are examined in the present office action.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program

listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The BRIEF DESCRIPTION OF THE DRAWINGS is objected to because Applicants have not included a BRIEF DESCRIPTION OF THE DRAWINGS for Figure 1.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

In addition, the date of filing of the instant application is incorrectly recited in the oath as February 4, 2002, instead of August 15, 2002.

Claims

4. Claim 7 is objected to for misspelling Brassicaceae.

Claim 7 is objected to for not including the recitation --a member of the-- between "is" and "Brassicacea".

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence, or wherein said nucleic acid sequence encodes a mutant protein comprising the peptide sequence Gly Tyr X_1Val Glu X_2 in which X_2 represents an amino acid other than glutamic acid, or wherein X_2 represents a basic amino acid, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4; a plant with reduced development comprising said nucleic acid sequence.

Applicants isolated their invention from dwarf plants of the "STELLAR" rapeseed line. The DNA sequence comprises 1716 bp coding sequence listed in SEQ ID NO:1 encoding the BZH polypeptide comprising 572 amino acids of SEQ ID NO:2. Applicants disclose the mutant gene contains a G to A substitution at position 1695 which creates a Glu to Lys amino acid change at position 546, whose sequences are set forth in SEQ ID NO:3 and 4, respectively (pages 7-8, Example 1).

The Applicants do not identify essential regions of the BZH protein encoded by SEQ ID NO:1, nor do Applicants describe a representative number of polynucleotide sequences that encode any protein comprising the peptide sequence of SEQ ID NO:5 that encodes a functional BZH protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly

and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a BZH protein falling within the scope of the claimed genus of polynucleotides which encode the peptide sequence of SEQ ID NO:5. Applicants only describe a single wild-type and mutant sequence of SEQ ID NO:1 and 3, respectively. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the BZH protein, it remains unclear what features identify a rapeseed BZH protein. Since the genus of BZH proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

6. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence, or wherein said nucleic acid sequence encodes a mutant protein comprising the peptide sequence Gly Tyr X_1 Val Glu X_2 in which X_2 represents an amino acid other than glutamic acid, or wherein X_2 represents a basic amino acid, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4; a plant with reduced development comprising said nucleic acid sequence.

For purposes of examination in regards to the enablement rejection, the Office interprets the claims to read on transforming a plant with any of Applicants' sequences.

Applicants define "modification of the sequence" to mean the substitution of one or more amino acids of said sequence, the insertion of one or more amino acids into this sequence, or the deletion of all or part of said sequence (page 5, lines 5-10). Given this meaning of "modification of the sequence", the office interprets this to read on any amino acid sequence.

Applicants isolated their invention from dwarf plants of the "STELLAR" rapeseed line. The DNA sequence comprises 1716 bp coding sequence listed in SEQ ID NO:1 encoding the BZH polypeptide comprising 572 amino acids of SEQ ID NO:2. Applicants disclose the mutant gene contains a G to A substitution at position 1695 which creates a Glu to Lys amino acid change at position 546, whose sequences are set forth in SEQ ID NO:3 and 4, respectively (pages 7-8, Example 1).

Applicants have not reduced to practice their invention. They have only taught cloning the wild-type and mutant BZH gene. They have not taught any of the procedures that are required for introducing the cloned gene into any plant, i.e., subcloning, bacterial transformation, plant transformation, or selection. In addition, Applicants have not taught how transforming any plant with a wild-type or mutant gene will produce a desired effect, i.e., producing a dwarf plant. It is not clear how transforming a plant with the wild-type gene, or a mutant gene, will produce a dominant negative effect or any effect.

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language, that gives the expected results when transformed into a plant. Transforming plants with heterologous genes

that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by designing non-disclosed fragments of SEQ ID NO:4 as probes or by designing primers to undisclosed regions of SEQ ID NO:4 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce dwarf plants.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Peng et al (1997, Genes & Development 11:3194-3205).

The claims are drawn to a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence; a plant with reduced development comprising said nucleic acid sequence, or wherein the plant is from the family Brassicacea.

Applicants define "modification of the sequence" to mean the substitution of one or more amino acids of said sequence, the insertion of one or more amino acids into this sequence, or the deletion of all or part of said sequence (page 5, lines 5-10). Given this meaning of "modification of the sequence", the office interprets this to read on any amino acid sequence.

Peng et al disclose a nucleic acid sequence encoding a protein of the GRAS family having a modification of the peptide sequence Gly Tyr X_1 Val Glu Glu in which more than one of the amino acids has been deleted (see page 3197, Figure 2 and page 3203, "Note added in proof". The sequence of Peng et al is an example of a GRAS protein because Applicants disclose that GAI is a member of the GRAS family of proteins (see paragraph bridging pages 2-3 of the specification). Peng et al disclose a *gai* mutant Arabidopsis plant exhibiting reduced development (page 3196, Figure 1) and as such, Peng et al anticipate the claimed invention.

8. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Foisset et al (1995, Theor. Appl. Genet. 91(5):756-761, listed in the IDS).

The claims are drawn to a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence, or wherein said nucleic acid sequence encodes a mutant protein comprising the peptide sequence Gly Tyr X_1 Val Glu X_2 in which X_2 represents an amino acid other than glutamic acid, or wherein X_2 represents a basic amino acid, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4; a plant with reduced development comprising said nucleic acid sequence.

Foisset et al disclose a dwarf Brassica napus plant comprising a mutant *breizh* (*bzh*) gene. Because of Applicants' admitted statement "The inventors have now characterized and sequenced the *BZH* gene of *B. napus*, and its mutant allele *bzh*, associated with the dwarf phenotype previously observed by Foisset et al (1995, ...) (page 3, lilnes 30-33), and because Applicants' claims read on the endogenous gene and not to a gene that has been isolated (as discussed below), Foisset et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-11 are directed to non-statutory subject matter. This rejection is made because the claims as written, do not sufficiently distinguish over nucleic acids, and plants as they exist

naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
July 19, 2005

ELIZABETH MCELWAIN
PRIMARY EXAMINER